

○ Institutional Guidelines for Animal Care and Use at Tokai University

Chapter 1. General Provisions

(Purpose and Basic Principles)

Article 1

This Regulation, established in accordance with the *Act on Welfare and Management of Animals* (Act No. 105 of 1973; hereinafter “the Act”), the *Standards relating to the Care and Keeping and Reducing Pain of Laboratory Animals* (Ministry of the Environment Notification No. 88 of 2006; hereinafter “Care and Management Standards”), and the *Fundamental Guidelines for Proper Conduct of Animal Experiments and Related Activities in Academic Research Institutions* (Ministry of Education, Culture, Sports, Science and Technology Notification No. 71 of 2006; hereinafter “Fundamental Guidelines”), and with reference to the *Guidelines for Proper Conduct of Animal Experiments* prepared by the Science Council of Japan (June 2006; hereinafter “Guidelines”), stipulates the necessary provisions for ensuring the appropriate conduct of animal experiments and the care and housing of laboratory animals at Tokai University (hereinafter “the University”).

These provisions define the responsibilities of the President, the establishment and operation of the Institutional Animal Care and Use Committee, the approval process for animal experiment plans, and the management of laboratory animals and related facilities. The aim is to ensure scientific integrity, uphold animal welfare, promote environmental conservation, and safeguard the health and safety of all personnel engaged in animal experimentation.

In addition to the Act, the Care and Management Standards, the Fundamental Guidelines, and the *Guidelines for Methods of Humane Killing of Animals* (Prime Minister’s Office Notification No. 40 of 1995; hereinafter “Humane Killing Guidelines”), all animal experiments shall be conducted in accordance with this Regulation.

Animal experiments must adhere to the Three Rs principle:

- **Replacement**– use alternatives to animal wherever possible while achieving the scientific objective;
- **Reduction**– use the minimum number of animals necessary to achieve valid results; and
- **Refinement**– minimize pain and distress to the extent compatible with scientific objectives.

In the care and housing of laboratory animals, consideration shall be given to the “*Five Freedoms*”—freedom from hunger and thirst; discomfort; pain, injury, or disease; fear and distress; and freedom to express normal behavior—to the extent possible while achieving the scientific purpose.

(Definitions)

Article 2

For the purposes of this Regulation, the following definitions apply:

1. **Animal experiments, etc.** – the use of animals for education, research, testing, biological production, or other scientific purposes.
2. **Care and housing facility**– any facility or equipment used for the long-term rearing or housing of laboratory animals or for conducting animal experiments.
3. **Animal experiment room**– a laboratory where experimental procedures are performed on laboratory animals (including temporary housing for up to 48 h, in principle).
4. **Facilities, etc.** – includes both care and housing facilities and animal experiment rooms.
5. **Laboratory animals** – mammals, birds, reptiles, and amphibians reared or housed for animal experiments, including those in transit to such facilities.
6. **Animal experiment plan**– a formal plan outlining the implementation of animal experiments.
7. **Animal experiment implementer**– a person conducting animal experiments.
8. **Animal experiment supervisor**– an implementer responsible for overseeing the conduct of animal experiments.
9. **Manager**– a person designated by the President to manage laboratory animals and related facilities.
10. **Laboratory animal facility manager**– a person assisting the manager, with expertise in laboratory animal care, responsible for managing such animals.
11. **Animal room supervisor**– a person coordinating among implementers using each care and housing facility and managing the animals therein.
12. **Animal experiment room representative**– a person coordinating among implementers using each animal experiment room and managing its use.
13. **Caretaker**– a person responsible for daily care and housing of laboratory animals in cooperation with the facility manager or implementer.

14. **Manager, etc.** – collectively refers to managers, facility managers, animal room supervisors, experiment room representatives, implementers, and caretakers.
 15. **Laws and regulations**– the Act, the Care and Management Standards, and other laws and regulations relating to animal experimentation.
 16. **Other relevant guidelines, etc.**– including the *Fundamental Guidelines for Proper Conduct of Animal Experiments and Related Activities in Institutions under the Jurisdiction of the Ministry of Health, Labour and Welfare* (MHLW Notification, 2015), the *Fundamental Guidelines for Proper Conduct of Animal Experiments and Related Activities in Research Institutions under the Jurisdiction of the Ministry of Agriculture, Forestry and Fisheries* (MAFF Notification, 2006), the *Humane Killing Guidelines*, and the *Guidelines*.
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Chapter 2. Scope of Application

Article 3

This Regulation applies to all animal experiments involving live mammals, birds, reptiles, and amphibians conducted at the University.

1. When an Animal Experiment Supervisor conducts experiments at external institutions, such experiments must comply with the relevant institution's animal experimentation guidelines.
2. If an Animal Experiment Supervisor outsources animal experiments to another institution, they must confirm that the experiments are conducted appropriately in accordance with the relevant institution's guidelines.

3. When using livestock in animal experiments, the Animal Experiment Supervisor must ensure compliance with the *Act on Domestic Animal Infectious Diseases Control* (Act No. 166 of 1951), *Standards for Rearing and Custody of Industrial Animals* (Ministry of the Environment Notification No. 85 of 2013), and the Guidelines.
 4. When using exhibition animals for experiments, such experiments must comply with the *Standards for the Rearing and Custody of Exhibition Animals* (Ministry of the Environment Notification No. 33 of 2004) and the Guidelines.
 5. When using wild animals for experiments, the Animal Experiment Supervisor must ensure compliance with applicable laws and regulations, including the *Law for the Protection of Cultural Properties* (Act No. 214 of 1950), the *Act on Conservation of Endangered Species of Wild Fauna and Flora* (Act No. 75 of 1992), the *Act on the Protection and Management of Wild Birds and Mammals and Hunting* (Act No. 88 of 2002), the *Invasive Alien Species Act* (Act No. 78 of 2004), and the Guidelines, etc., with due consideration for the characteristics of wild animals and the principles of nature conservation.
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Chapter 3. Organization

(Responsibilities of the President)

Article 4

The President, as the ultimate authority, shall oversee the proper conduct of animal experiments and the care and housing of laboratory animals at the University. The President's responsibilities include the following:

1. Maintaining and improving facilities and related infrastructure.
2. Approving animal experiment plans and monitoring their implementation and results
3. Implementing corrective measures based on monitoring outcomes.
4. Approving the establishment or closure of facilities.
5. Ensuring safety management related to animal experiments.
6. Providing education and training for personnel involved in animal experimentation.
7. Conducting self-inspection, evaluation, and information disclosure.
8. Facilitating external verification or evaluation by independent organizations.
9. Taking other measures necessary for the proper conduct of animal experiments.
10. The President shall establish, as an advisory body, the **Institutional Animal Care and Use Committee** (hereinafter “the Committee”), as prescribed in Chapter 4, to report on and advise concerning the responsibilities listed above.
11. The President may, when necessary, establish under the Committee a **Specialist Committee for Animal Experiments** (hereinafter “the Specialist Committee”) to support the effective and proper conduct of animal experiments at the University.
12. The President shall also establish, as an organization independent from the Committee, the **Animal Experiment Evaluation Committee** (hereinafter “the Evaluation Committee”), as prescribed in Chapter 5. This Committee shall conduct inspections and evaluations—drawing on experts from the humanities, social sciences, and external institutions—regarding the appropriateness of animal experiments and the care and housing of laboratory animals at the University.
13. To ensure proper care and management of laboratory animals, the President shall appoint a **Laboratory Animal Facility Manager** for each campus with care and housing

facilities, and may appoint **Animal Room Supervisors** for individual facilities as necessary.

Chapter 4. Institutional Animal Care and Use Committee

(Role of the Committee)

Article 5

Upon consultation with the President, the Committee shall review or investigate the following matters and make recommendations to the President:

1. Compliance of animal experiment plans with applicable laws, regulations, the Guidelines, and this Regulation.
2. Implementation status and results of approved animal experiment plans.
3. Establishment or abolition of facilities, and the status of laboratory animal care and housing.
4. Content and structure of education and training programs on the proper handling of animal experiments and laboratory animals, and on compliance with relevant laws, regulations, and the Guidelines.
5. Self-inspection and evaluation, verification by external organizations, and information disclosure.
6. Other matters necessary to ensure the proper conduct of animal experiments.

7. As necessary, the Committee may propose to the President the establishment of a Specialist Committee and shall endeavor to ensure that animal experiments are conducted smoothly and appropriately.
 8. Matters necessary for the operation of the Specialist Committee shall be determined separately by the Committee.
 9. To expedite deliberations on the matters listed in Paragraph 1, the Committee shall establish an Operations and Review Subcommittee.
 10. Matters necessary for the operation of the subcommittee shall be determined separately by the Committee.
 11. The Committee shall, as necessary, exchange information and cooperate with other committees related to animal experiments, particularly those requiring special attention to safety management.
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(Composition of the Committee)

Article 6

The Committee shall consist of members appointed by the President from among the following:

1. One Laboratory Animal Facility Manager from each campus where animal experiments are conducted.
2. One faculty member involved in animal experiments from each campus.
3. Several members with expertise in animal experiments.
4. Several members with expertise in laboratory animal science.
5. A few persons with expertise in infectious diseases.

6. A few persons with expertise in genetic engineering experiments.
 7. A few persons with expertise in handling chemical substances.
 8. A few persons with relevant academic knowledge and experience.
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(Chairperson, etc.)

Article 7

1. The Committee shall have a Chairperson, elected from among its members.
 2. The Committee shall have a Vice-Chairperson, also elected from among its members.
 3. The Chairperson shall preside over the Committee.
 4. The Vice-Chairperson shall assist the Chairperson and, when the Chairperson is unable to perform their duties, shall act on their behalf.
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(Term of Office of Members)

Article 8

1. The term of office for members shall be two years; reappointment is permitted.
 2. In the event of a vacancy, the President shall appoint a replacement member in accordance with the composition specified in Article 6. The replacement member shall serve for the remainder of their predecessor's term.
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(Quorum and Deliberations)

Article 9

1. Deliberations on the matters specified in Article 5, Paragraph 1 shall be valid with the attendance of at least two-thirds of all members, and a two-thirds majority of those present shall adopt resolutions.
 2. In the case of deliberations conducted by email or other electronic means, resolutions shall be valid with responses from at least two-thirds of all members and adopted by a two-thirds majority of respondents.
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(Administrative Affairs)

Article 10

1. The administrative affairs of the Committee shall be handled by the President's office.
 2. Administrative staff shall prepare and maintain minutes and other records related to Committee meetings.
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Chapter 5. Animal Experiment Evaluation Committee

(Role of the Evaluation Committee)

Article 11

Upon consultation with the President, the Evaluation Committee shall deliberate on the following matters, make recommendations to the President, and provide proposals to the Committee:

1. Verification of self-inspection and evaluation reports concerning animal experiments.
 2. Preparation of verification result reports related to animal experiments.
 3. Verification and review by external organizations.
 4. Other matters necessary to ensure the proper conduct of animal experiments.
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(Composition of the Evaluation Committee)

Article 12

The Evaluation Committee shall consist of members appointed by the President from among the following. Members of the Committee shall not concurrently serve on the Evaluation Committee:

1. The Director of the Office of the President (in charge of Research Promotion and Industry-Academia Collaboration).
 2. A few members with expertise in animal experiments.
 3. A few members with expertise in natural sciences than those in Item 2.
 4. A few members with expertise in the humanities and social sciences.
 5. A few external experts.
 6. Other persons deemed necessary by the President.
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(Chairperson of the Evaluation Committee)

Article 13

1. The Evaluation Committee shall have a Chairperson, elected from among its members.
 2. The Chairperson shall preside over the Evaluation Committee.
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(Term of Office of Members)

Article 14

1. The term of office for members shall be two years; reappointment is permitted.
 2. In the event of a vacancy, the President shall appoint a replacement member in accordance with the composition specified in Article 12. The replacement member shall serve the remainder of their predecessor's term.
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(Quorum and Deliberations)

Article 15

1. Deliberations on the matters specified in Article 11, Paragraph 1 shall be valid with the attendance of two-thirds of all members, and a two-thirds majority of those present shall adopt resolutions.
 2. In the case of deliberations conducted by email, resolutions shall be valid with responses from two-thirds of all members, and adopted by a two-thirds majority of respondents.
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(Administrative Affairs)

Article 16

1. The president's office handles the administrative affairs of the Evaluation Committee.
 2. Administrative staff shall prepare and maintain the minutes and other records related to Evaluation Committee meetings.
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Chapter 6. Implementation of Animal Experiments.

(Formulation, Review, and Approval of Animal Experiment Plans)

Article 17

1. The Animal Experiment Supervisor shall prepare an animal experiment plan, considering the following factors to ensure scientific reliability and ethical conduct, and shall submit the plan to the President using the prescribed form:
 - Purpose, significance, and necessity of the research.
 - Appropriate use of laboratory animals, including the use of alternative methods wherever possible.
 - Selection of animal species appropriate for the purpose; consideration of factors such as the number of animals that influence the accuracy and reproducibility of results, genetic and microbiological quality, and housing conditions; and minimization of animal use.
 - Procedures designed to minimize pain and distress to the extent necessary for scientific purposes.

- For high-pain procedures (e.g., lethal toxicity tests, infection experiments, or radiation exposure), establishment of humane endpoints at the planning stage.
2. Upon receiving the application, the President shall determine whether to approve or reject the plan after review by the Committee and shall notify the Animal Experiment Supervisor of the result.
 3. Approval of an animal experiment plan shall be valid until the end of the relevant fiscal year.
 4. No experiments may be conducted without the President's approval of the plan.
 5. In the case of conducting the following activities at other institutions or in the field, as described in Article 3, Paragraphs 2 to 6, the Animal Experiment Supervisor shall apply in the same manner and obtain the President's approval:
 - Animal experiments using primates.
 - Animal experiments using livestock.
 - Animal experiments using exhibition animals.
 - Animal experiments involving the capture of wild animals or the installation of temporary or permanent enclosures to observe their ecology or behavior.
 - Other cases deemed necessary by the Committee.
 6. If changes are made to an approved animal experiment plan, the Animal Experiment Supervisor shall reapply in the same manner as in Paragraph 1 and obtain approval for the revised plan.
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(Experimental Procedures)

Article 18

Animal Experiment Implementers shall comply with all relevant laws, regulations, and the Guidelines, and in particular, shall:

1. Use animals only to the extent necessary to achieve the objectives of the experiment.
2. Conduct experiments in appropriately maintained facilities using proper equipment.
3. Comply with the approved animal experiment plan and observe the following:
 - a. Use appropriate anesthetics and analgesics.
 - b. Follow criteria for interruption or termination of the experiment (including humane endpoints) and, where appropriate, perform euthanasia.
 - c. Minimize experiment duration and determine appropriate termination timing.
 - d. Provide adequate measures such as thermal support and postoperative care.
 - e. Perform euthanasia in accordance with the *Humane Killing Guidelines* and relevant international standards.
4. Exercise special caution and comply with relevant laws and institutional rules when conducting experiments involving pathogens, genetically modified animals, or hazardous materials..
5. Ensure the safety and health of implementers in experiments that may affect human health or the surrounding environment.
6. Use and store narcotics and other regulated substances in accordance with applicable laws and regulations.

7. Implement measures to prevent escape of genetically modified or invasive alien species, considering facility and equipment conditions.
 8. Acquire necessary experimental techniques and competencies in advance.
 9. Perform highly invasive or major survival surgeries only under the guidance of experienced personnel.
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(Reporting of Results)

Article 19

1. Upon completion or termination of experiments conducted under an approved animal experiment plan, the Animal Experiment Supervisor shall report to the President, using the prescribed form, details such as the number of animals used, any changes to the plan, and research outcomes.
 2. For animal experiment plans extending over multiple fiscal years, the Animal Experiment Supervisor shall submit an annual report to the President at the beginning of each fiscal year using the prescribed form.
 3. The President may seek the Committee's opinion on the reported results.
 4. Based on the Committee's advice, the President shall, as necessary, implement measures to improve the proper conduct of animal experiments.
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Chapter 7. Rearing and Housing of Laboratory Animals

(Preparation and Dissemination of Manuals)

Article 20

The Manager and the Laboratory Animal Facility Manager shall prepare rearing and housing manuals (standard operating procedures) based on the Act and the Care and Management Standards. They shall ensure that Animal Room Supervisors, Animal Experiment Implementers, and Caretakers are informed of and comply with these manuals.

(Maintenance of Health and Safety of Laboratory Animals)

Article 21

The Laboratory Animal Facility Manager, Animal Room Supervisors, Animal Experiment Implementers, and Caretakers shall comply with the Care and Management Standards and strive to maintain the health and safety of laboratory animals.

(Introduction of Laboratory Animals)

Article 22

1. The Manager shall ensure that laboratory animals are obtained only from institutions properly managed in accordance with relevant laws, regulations, and the Guidelines.
2. Upon introduction, the Laboratory Animal Facility Manager and Animal Room Supervisors shall conduct appropriate quarantine (including document-based quarantine) and isolation housing as necessary.

3. The Laboratory Animal Facility Manager and Animal Room Supervisors shall take measures to acclimate laboratory animals to their new environment.
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(Methods of Rearing and Housing)

Article 23

1. The Laboratory Animal Facility Manager, Animal Room Supervisors, Animal Experiment Implementers, and Caretakers shall ensure appropriate feeding, watering, health management, and environmental conditions suitable for each species, considering their physiology, ecology, and habits, without interfering with the experiment's purpose.
 2. The Laboratory Animal Facility Manager and Animal Room Supervisors shall confirm the number and condition of animals through routine management and periodic inspections of the facilities.
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(Health Management)

Article 24

1. The Laboratory Animal Facility Manager, Animal Room Supervisors, Animal Experiment Implementers, and Caretakers shall conduct necessary health management to prevent injuries or diseases unrelated to the experiments.

2. If such injuries or diseases occur, the Laboratory Animal Facility Manager, Animal Room Supervisors, Animal Experiment Implementers, and Caretakers shall provide appropriate treatment, to the extent that it does not interfere with the purpose of the experiments.
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(Rearing of Multiple or Different Species of Animals)

Article 25

When different species or multiple groups of laboratory animals are reared and housed in the same facility, the Laboratory Animal Facility Manager, Animal Room Supervisors, Animal Experiment Implementers, and Caretakers shall ensure appropriate combinations that do not interfere with the experiments.

(Proper Record Management and Reporting)

Article 26

1. Managers shall maintain records on the sources, rearing history, and medical history of laboratory animals, and ensure appropriate record management.
2. Where technically feasible, Managers shall implement identification measures such as name tags, leg bands, or microchips for laboratory animals that may pose risks to humans.

3. The Manager and the Laboratory Animal Facility Manager shall annually report to the President, using the prescribed form, on the species and numbers of animals reared or housed, and compliance with the Care and Management Standards.
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(Provision of Information upon Transfer)

Article 27

The Managers, when transferring laboratory animals, shall provide recipients with information regarding the characteristics, rearing and housing methods, and infectious diseases of animals.

(Transportation)

Article 28

The Managers, when transporting laboratory animals, shall comply with Care and Management Standards, ensuring the health and safety of laboratory animals and preventing harm to humans.

Chapter 8. Facilities

(Establishment of Care and Housing Facilities)

Article 29

1. When establishing or modifying a care and housing facility, the Animal Room Supervisor shall obtain the Manager's permission and apply to the President using the prescribed form.
 2. The President shall instruct the Committee to inspect the proposed facility and, based on its advice, decide whether to approve or reject the application, notifying the relevant Animal Room Supervisor of the result.
 3. Laboratory animals shall not be reared, housed, or used in experiments in facilities not approved by the President.
 4. Based on reports from the Manager or Laboratory Animal Facility Manager, and with advice from the Committee or the Evaluation Committee, the President may instruct improvements to ensure proper rearing and housing of laboratory animals.
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(Requirements of Care and Housing Facilities)

Article 30

Care and housing facilities shall meet the following requirements:

1. Structures capable of maintaining appropriate temperature, humidity, ventilation, and lighting suited to the physiology, ecology, and habits of laboratory animals.
2. Equipment and capacity appropriate for the species and number of animals.
3. Sufficient space for natural movements, without interfering with the experiment's purpose.
4. Floors and walls designed for easy cleaning and maintenance of hygiene, with sanitary facilities for washing and disinfecting equipment.

5. Structural integrity to prevent animal escape, with established measures for recapture.
 6. Measures to prevent odor, noise, or waste from affecting the surrounding environment.
 7. Protection against bad weather, predators, and other hazards for outdoor housing.
 8. Compliance with relevant laws, regulations, and university rules for facilities involving experiments requiring special safety considerations (e.g., pathogens, genetically modified animals, hazardous physical or chemical materials), compliance with relevant laws, regulations, and related university rules.
 9. Appointment of a Laboratory Animal Facility Manager.
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(Establishment of Animal Experiment Rooms)

Article 31

1. When establishing or modifying an animal experiment room outside care and housing facilities, the Animal Experiment Room Representative shall obtain permission from the Manager and apply to the President using the prescribed form.
2. The President shall instruct the Committee to investigate the proposed room and, based on its advice, approve or reject the application and notify the relevant Animal Experiment Room Representative of the result.
3. No animal experiments (including temporary housing for up to 48 h in principle) may be conducted in facilities not approved by the President.
4. Based on reports from the Animal Experiment Room Representative and with advice from the Committee or the Evaluation Committee, the President may instruct improvements in the management of animal experiment rooms.

(Requirements of Animal Experiment Rooms)

Article 32

Animal experiment rooms shall meet the following requirements:

1. Structures strong enough to prevent animal escape, with an environment facilitating recapture if an escape occurs indoors.
2. Structures designed for easy cleaning and disinfection of excreta, blood, and other contaminants.
3. Cleanliness and measures to prevent of odors, noise, and waste from affecting the surrounding environment
4. Conditions maintaining appropriate temperature and animal health during procedures and temporary housing.
5. Compliance with relevant laws, regulations, and university rules for rooms used for experiments requiring special safety considerations (e.g., pathogens, genetically modified animals, hazardous materials).

(Maintenance and Improvement of Facilities)

Article 33

1. The Manager and Laboratory Animal Facility Manager shall maintain and improve facilities necessary for the proper management of laboratory animals and animal experiments.
 2. The Manager and Laboratory Animal Facility Manager shall ensure that facilities are appropriately maintained, considering the physiology, ecology, and habits of laboratory animals.
 3. The Manager and Laboratory Animal Facility Manager shall ensure that facilities are structured and managed to allow implementers and caretakers to work safely.
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(Abolition of Facilities)

Article 34

1. When abolishing facilities, the Animal Room Supervisor or Animal Experiment Room Representative shall notify the President using the prescribed form.
 2. The President shall instruct the Committee to inspect the facilities to be abolished and, based on its report, decide on approval.
 3. The Manager and the Laboratory Animal Facility Manager shall cooperate with Animal Experiment Supervisors to transfer laboratory animals to other approved facilities, as necessary.
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Chapter 9. Safety Management

(Prevention of Harm)

Article 35

1. The Manager and Laboratory Animal Facility Manager shall establish procedures in advance for capturing escaped laboratory animals.
2. If laboratory animals capable of harming humans escape, the Manager and Laboratory Animal Facility Manager shall promptly notify the relevant authorities.
3. The Manager and Laboratory Animal Facility Manager shall implement preventive measures and necessary health management to protect Animal Room Supervisors, Animal Experiment Implementers, and Caretakers from zoonoses, allergies, and injuries (e.g., bites), and shall take appropriate action if such incidents occur.
4. The Laboratory Animal Facility Manager, Animal Room Supervisors, Animal Experiment Implementers, and Caretakers shall share relevant information to prevent harm caused by laboratory animals.
5. The Laboratory Animal Facility Manager, Animal Experiment Implementers, and Caretakers shall provide guidance and reports as necessary through mutual information sharing.
6. When rearing or housing venomous snakes or other dangerous animals, the Manager and Laboratory Animal Facility Manager shall stipulate specific safety measures in accordance with the Care and Management Standards to prevent harm to humans.
7. The Managers shall ensure that individuals not involved in animal experiments do not come into contact with laboratory animals.

(Emergency Response)

Article 36

1. In cooperation with relevant administrative agencies, the Manager and Laboratory Animal Facility Manager shall prepare emergency response plans (such as emergency manuals) consistent with regional disaster prevention plans, addressing emergencies such as earthquakes or fires, and shall disseminate these to relevant personnel.
 2. In the event of an emergency, the Managers shall promptly work to protect laboratory animals and prevent harm to humans or environmental issues due to escaped animals.
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(Acquisition of Knowledge on Zoonoses)

Article 37

1. The Laboratory Animal Facility Manager, Animal Room Supervisors, Animal Experiment Implementers, and Caretakers shall acquire sufficient knowledge and stay informed regarding zoonoses.
 2. The Manager, Laboratory Animal Facility Manager, Animal Room Supervisors, and Animal Experiment Implementers shall establish communication systems with public health agencies to ensure prompt action in the event of a zoonotic outbreak.
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Chapter 10. Education and Training

Article 38

1. The President shall require the Laboratory Animal Facility Managers, Animal Room Supervisors, Animal Experiment Implementers, and Caretakers to complete prescribed education and training designed to ensure the proper conduct of animal experiments and to the appropriate rearing and housing of laboratory animals. Training shall include the following:
 - Laws, regulations, the Guidelines, etc., and University rules.
 - Fundamental methods of animal experimentation.
 - Basic principles of animal rearing and housing.
 - Safety assurance and management.
 - Zoonoses and related health risks.
 - Other matters necessary for the proper conduct of animal experiments.
 2. The President shall maintain records of training dates, content, instructors, and participants.
 3. The President shall ensure that appropriate education and training are provided for all relevant personnel.
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Chapter 11. Self-Inspection, Evaluation, and Verification

Article 39

1. The President shall instruct the Committee to conduct annual self-inspections and evaluations to ensure compliance with the Fundamental Guidelines and the Care and Management Standards, thereby maintaining transparency in animal experimentation.

2. The Committee shall evaluate the implementation of animal experiments and the rearing and housing of laboratory animals and report the results to the President.
 3. The Committee may require the Manager, Laboratory Animal Facility Manager, Animal Experiment Supervisor, and Caretakers to submit relevant materials for inspection and evaluation.
 4. The President shall ensure that the Evaluation Committee and external organizations verify the results of self-inspection and evaluation.
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Chapter 12. Information Disclosure

Article 40

The President shall disclose, at least once a year, information concerning animal experiments at the University by appropriate means, including:

1. The Regulation, results of inspections and evaluations, verification by external organizations, and the status of rearing and housing of laboratory animals, as exemplified in the Fundamental Guidelines.
 2. Items requested for disclosure by the Council of National University Corporation Animal Facilities and the Council of Public and Private University Animal Facilities.
 3. Results of inspections regarding compliance with the Care and Management Standards.
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Chapter 13. Sanctions

Article 41

1. The President may immediately suspend the animal experiments of any person who violates this Regulation, and prohibit the conduct of animal experiments for a specified period.
 2. In applying sanctions, the President may seek the advice of the Committee.
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Chapter 14. Supplementary Provisions

(Mutatis Mutandis Application)

Article 42

When animals other than those defined in Article 2, Item 5 are used for experiments, efforts shall be made to conduct them in accordance with the spirit of the Care and Management Standards.

(Exemptions)

Article 43

1. This Regulation shall not apply to the rearing or housing of animals for education or research in animal husbandry, breeding improvement of livestock species, or ecological

observation, unless invasive procedures (e.g., blood collection, artificial breeding, surgery, or pharmacological testing) are performed.

2. For livestock, care and housing shall comply with the *Standards for the Rearing and Custody of Industrial Animals* (Prime Minister's Office Notification No. 22 of 1987).
 3. For animals reared or housed for ecological observation, activities shall comply with the *Standards for the Rearing and Custody of Household Animals, etc.* (Ministry of the Environment Notification No. 37 of 2002).
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(Conformity)

Article 44

1. Specific methods concerning the proper conduct of animal experiments and the proper rearing and housing of laboratory animals at the University shall conform to the Guidelines.
 2. Specific methods for the proper rearing and housing of livestock at the University shall conform to the *Technical Guidelines for Rearing Management by Animal Species* (MAFF Notification, 2023).
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(Miscellaneous Provisions)

Article 45

The President shall determine matters not provided for in this Regulation separately.

(Amendment or Abolition)

Article 46

Any amendment or abolition of this Regulation shall be subject to deliberation by the Committee and the Evaluation Committee and shall require approval through the University's decision-making procedures.

Supplementary Provisions (April 1, 2024)

1. This Regulation shall come into effect on April 1, 2024.
2. This Regulation consolidates and revises the University's previous animal experiment-related regulations.
3. Upon enactment, the following regulations shall be abolished:
 - Tokai University Animal Experiment Guidelines (established April 1, 2007)
 - Institutional Animal Care and Use Committee Regulations at Tokai University (established April 1, 2007)
 - Tokai University Animal Experiment Evaluation Committee Regulations (established April 1, 2015)
 - Standards concerning the Structure and Use of Animal Experiment Facilities at Tokai University (established October 1, 2008)
 - Requirements concerning the Rearing and Housing of Livestock as Laboratory Animals at Tokai University (established October 1, 2008)

Supplementary Provisions (April 1, 2025)

This Regulation shall come into effect on April 1, 2025.